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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,377	01/04/2006	Jeffrey S. Glenn	STAN-316	7561
79974 7590 04/13/2009 Stanford University Office of Technology Licensing Bozicevic, Field & Francis LLP 1900 University Avenue Suite 200 East Palo Alto, CA 94303				
			EXAMINER	
			LUCAS, ZACHARIAH	
		ART UNIT	PAPER NUMBER	
		1648		
		MAIL DATE	DELIVERY MODE	
		04/13/2009 PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/528,377

**Applicant(s)**

GLENN ET AL.

**Examiner**

Zachariah Lucas

**Art Unit**

1648

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,6,7,9,10 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,9,10 and 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1, 3, 6, 7, 9, 10, 22-24 are pending and under consideration.
2. In the prior action, mailed on January 29, 2009, claims 1, 3, 5-7, 9, 10, 22, and 23 were pending and in the application and rejected.
3. In the Response of March 27, 2009, the Applicant amended claims 1, 9, 10, and 22; cancelled claim 5; and added new claim 24.

#### *Claim Objections*

4. **(New Objection)** Claim 9 is objected to because of the following informalities: the claim appears as though it intends to read on a method wherein the determination as to the effects of the candidate agent on HCV replication is made by determining the effect of the agent on the replication of a subgenomic or full-length replicon in a cell. At present the claim appears to be attempting to redefine HCV (the acronym for the virus itself) as including the polynucleotide replicons used in the art as a representative for the virus in certain replication assays. Thus, the claim would properly read by describing the method as indicated above, rather than attempting to define what is meant by reference to HCV.

Appropriate correction is required.

5. **(New Objection)** Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent

form, or rewrite the claim(s) in independent form. This claim depends from claim 9, and indicates that “said HCV is live virus or a replicon thereof.” However, claim 9 requires the use of a replicon. Claim 23 therefore appears to read on embodiments excluded by the claim from which it depends. It appears that the claim should depend from claim 24.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(New Rejection- Necessitated by Amendment)** Claims 1, 6, 7, 9, 10, and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to read on a method comprising determining the effect of a candidate agent on “a nucleotide binding activity” or on “an HCV RNA binding activity” of said NS4B protein,” the method comprising contacting an HCV nucleotide-binding NS4B protein with HCV RNA and a candidate agent. Pages 14 (lines 25-26) and 16 (lines 1925) of the application indicate that the phrase an HCV nucleotide-binding NS4B protein refers to the full-length HCV NS4B protein encoded by the virus. The claims are rejected as lacking adequate support for the full scope of the claimed methods.

A rejection was previously made on the grounds that the application failed to provide adequate support with respect to methods for screening for “an HCV RNA binding activity” of NS4B (in a prior version of claim 5 of the application). See, Office Action mailed on August 23, 2007, pages 8-9. The rejection is therefore reinstated in view of the amendment of claim 1 to incorporate the previously rejected language.

Similarly, the teachings in the application and art also fail to indicate what other activities are performed by NS4B which qualify as “a nucleotide binding activity” and which those in the art would be capable of screening for. In absence of knowledge in the art, or disclosure in the application, of such activities of the NS4B protein, those in the art would not know what activities to screen for, and thus would not have been placed in possession of the full scope of the claimed methods.

It is suggested that the claim be amended to refer to determining the effects of the candidate agent on NS4B “nucleotide binding” or “HCV RNA binding” rather than on “a nucleotide binding activity” or on “an HCV RNA binding activity” of the protein.

#### ***Claim Rejections - 35 USC § 103***

8. **(Prior Rejections- Withdrawn)** Claims 8-10, 22, and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Del Vecchio in view of Jin, Kadaré, and Rodriguez as applied to claims 1-4 previously, and further in view of Wimmer et al. (U.S. 2002/0098202). Claims 6 and 7 were rejected under 35 U.S.C. 103(a) as being unpatentable over Del Vecchio in view of Jin, Kadaré, and Rodriguez as applied to claims 1-4 above, and further in view of Morouianu et al. (PNAS 92:4318-22). In view of the amendments of the claims requiring the

Art Unit: 1648

additional determination of the effect of the agent on an RNA binding activity of NS4B, the rejections are withdrawn.

### *Conclusion*

9. No claims are allowed.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/

Primary Examiner, Art Unit 1648